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ATTORNEY DOCKET NO. CONFIRMATION NO. FIRST NAMED INVENTOR APPLICATION NO. FILING DATE 650053.91649 6714 11/05/2003 Fritz Sieber 10/701,870 **EXAMINER** 11/04/2005 7590 TSAY, MARSHA M Zhibin Ren Quarles & Brady LLP PAPER NUMBER ART UNIT 411 East Wisconsin Avenue Milwaukee, WI 53202-4497 1653

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)
Office Action Summary		10/701,870	SIEBER ET AL.
		Examiner	Art Unit
		Marsha M. Tsay	1653
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status			
1)⊠ Respons	sive to communication(s) filed on <u>17 O</u>	ctober 2005.	
2a) ☐ This acti	· · ·	action is non-final.	
<u> </u>	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
·	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims			
	Claim(s) 2,4-12 and 26-30 is/are pending in the application.		
	4a) Of the above claim(s) is/are withdrawn from consideration.		
	5) Claim(s) <u>26-30</u> is/are allowed.		
<u> </u>	Claim(s) <u>2,4-6,8 and 9</u> is/are rejected.		
·	7) Claim(s) 7 and 10-12 is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.			
Application Papers			
9) The specification is objected to by the Examiner.			
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).			
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.			
Priority under 35 U.S.C. § 119			
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>			
	person's Patent Drawing Review (PTO-948) losure Statement(s) (PTO-1449 or PTO/SB/08)	4)  Interview Summary Paper No(s)/Mail D 5)  Notice of Informal F 6)  Other:	

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This Office Action is in response to Applicant's amendment after final received October 17, 2005. Claims 1, 3, 13-25, 31-51 are canceled. Claims 2, 4-12, 26-30 are pending and currently under examination.

The indicated allowability of claims 2, 4-12 in the Office Action mailed August 25, 2005 is withdrawn in view of newly discovered references. Rejections based on the cited reference(s) follow.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 4-6, 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Labrenz et al. (2000 Science 290(5497): 1744-1747). Claims 4-6 are drawn to a pharmaceutical composition comprising elemental selenium (Se(0)) particles having a diameter of 0.4 to 5 nanometers. On page 8 of the specification, section [00042], Applicants disclose the Se(0) particles used in the instant invention typically have a diameter of 0.4 to 50 nanometers, 0.4 to 5 nanometers, or 0.4 to 1 nanometer. This appears to be a general statement describing the Se(0) particles and does not appear to be a limiting factor. This is evidenced by the fact that nowhere in the specification does it indicate an actual measurement of the Se(0) particles used in the instant

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invention. Therefore, the instant claims can be anticipated by a composition comprising elemental Se and/or a colloid Se.

Labrenz et al. teach micrometer-scale, spherical aggregates of 2- to 5-nanometer diameter sphalerite (ZnS) particles are formed within natural biofilms of sulfate-reducing bacteria (p. 1744). The biofims studied by Labrenz et al. were collected from a flooded tunnel within carbonate rocks, wherein the water meets drinking standards (p. 1744-45, table 1; claims 4-5). High-resolution TEM images reveal that the diameter of particles within aggregates is ~3 nm, therefore ~3-um-diameter aggregates consist of about a billion ZnS particles (p. 1744-1745; claims 4-5). Labrenz et al. teach synchrotron-based x-ray microprobe analyses indicated that sphalerite contains As and Se (p. 1745-46, table 2; claims 4-5).

Claims 2, 4-6, 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Lou et al. (1993 Clinical Chemistry 39(4): 619-624). Lou et al. teach a rapid, one-step competitive immunochromatographic assay to measure lipoprotein(a) (Lp(a)) in plasma. To prepare one component of the assay strip, Lou et al. teach 1 mL of colloidal selenium solution was adjusted to pH 8.0 by adding 50 uL borate buffer, followed by the addition of 10 ug of Lp(a) protein (p. 620, col. 2; claims 2, 4-6, 8-9). The colloidal mixture was gently vortex-mixed for 2 min. and added to 10 uL of 100 g/L polyethylene glycol to block and stabilize the Lp(a)-coated colloidal selenium (620; claims 2, 4-6, 8-9).

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Claims 7, 10-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 26-30 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 28, 2005

KAREN COCHRANE CARLSON, PH.D

PRIMARY EXAMINER